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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SHAFFER, RICHARD R	

ART UNIT	PAPER NUMBER
3775	

MAIL DATE	DELIVERY MODE
03/31/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/766,911	SGIER ET AL.	
	Examiner	Art Unit	
	Richard Shaffer	3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22,24 and 36-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22,24 and 36-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

Applicant's claim amendments filed on March 3rd, 2009 are acknowledged by the examiner. Due to the cancellation of claim 23, the previous 35 U.S.C. 112, first paragraph rejections are now moot.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-22, 24 and 36-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin et al (US 5,368,594) in view of Vignaud et al (US Patent 5,176,680) and in further view of Schlapfer et al (US Patent 5,501,684) and Petreto (US Patent 5,938,663)..

Martin et al disclose a vertebral arthrodesis device (**Figures 1-4**) comprising: at least two pins (**3**); screws (**5b**) having a head with a cavity (**11**) to receive a pin (**3**); the head having two lateral threaded holes receiving two threaded fastening screws (**14**); a cap (**12**) configured to contact and secure the rod with the cavity (**11**) due to inwardly inclined side walls (**12a**); the cap (**12**) has a conical shape (see **Figure 4** with the inwardly tapered top portion consistent with **element 17 of applicant's device** as shown in **Figures 2 and 3**); the cavity (**11**) snapping onto the pin (**5**, **See Column 1, Line 63 through Column 2, Line 13 and Column 3, Line 63 through Column 4, Line**

6 discussing "clipping the rods into the cavities prior to applying caps 12); and the cavity is able to perpendicular flex (relative to the longitudinal axis of the arthrodesis device) because of two inward pointing slots (**13, Figure 2**).

Martin et al fail to disclose spherical lateral undercuts to allow pivoting, a ring placed along the pin and a spherical cavity allowing for angular adjustments of the pin(s) (spinal rod) in multiple planes prior to immobilization with a ring about it.

Vignaud et al teach a similar device with a bone-anchoring portion (**1**), a split ring (**9**) slidable along the length of the spinal rod (**6**), clamping means (**7**, **8**, and **18**), spherical cavity (as seen in **Figure 2**), and spherical (are rounded) lateral undercuts (**Figures 1 and 3**, the areas of parts **5** and **17**). The ring and lateral undercuts allow for pivoting of the spinal rod as shown in **Figure 2**. It is explained (**Column 1, Lines 1-20**) that fixed systems only allow rods to be placed perpendicular to pedicle screws and thus make it difficult to re-establish physiological curves of the spine. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Martin et al with the split ring and lateral undercuts of Vignaud to allow for placement of a rod in an orientation other than perpendicular to the pedicle screw in order to facilitate the positioning of the spine.

Schlapfer et al teach in **Figure 2** a sliding ring to allow pivoting of the screw in a bone fixation device longitudinal cuts none of which go through entirely, but initiate at alternating ends of the ring. This allows greater flexibility of the ring while maintaining integrity. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the split ring in the combination of Martin et al and

Vignaud et al with the teaching of Schlapfer et al to allow greater flexibility of the spinal rod while maintaining integrity.

Petreto teaches (**Figure 2; Column 1, Line 8 through Column 2, Line 5**) a device which allows orientation of the pin in all directions (multiple planes) by allowing clearance (in the shape of a spherical recess as shown in Figures 3 and 5) in all directions about the rod, not only vertically as shown in Vignaud et al. It would have been obvious to one having ordinary skill in the art to design the combination of Martin et al, Vignaud et al and Schlapfer et al with the ability to allow other planes of angulation as a matter of mere substitution for the single planar angulation taught by Vignaud et al with predictable results.

Response to Arguments

Applicant's arguments filed on March 3rd, 2009 have been fully considered but they are not persuasive. Applicant contends that the combination of Martin et al, Vignaud et al, Schlapfer et al and Petreto fail to disclose and teach lateral recesses in the cavity delimited by the head as well as allowing angular clearance in multiple directions. In Martin et al, the structure holding the rod is formed integrally with the screw which is also the case with Vignaud et al which does teach allowing vertical angular motion due to the shape of the screw head. Petreto teaches a connector with spherical recesses allowing multiple plane angulations which are placed on top of a screw head thereby performing the same function as the integral structure of Martin et al and Vignaud et al. Therefore, all that is gleaned from the Petreto reference for modifying Martin et al and Vignaud et al is to include a spherical recess on both sides in

order to allow angular motion in multiple planes instead of none or one. The structures holding the rod in all three references are analogous to one another and merely substituting one for the other is obvious to one having ordinary skill in the art as being equivalent structures for supporting a spinal rod, however, the motion imparted by both the structures of Vignaud et al and Petreto are beneficial in that they allow rods at various orientations to be held by the screw without excessive bending of the spinal rods which reduces the integrity of the spinal rods.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard Shaffer whose telephone number is (571)272-8683. The examiner can normally be reached on Monday-Friday (7am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Richard Shaffer/
Examiner, Art Unit 3775
/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733